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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CRYOVAC, INC., Plaintiff/Counter-Defendant)
v.)) Civil Action No. 04-1278-KAJ
PECHINEY PLASTIC PACKAGING, INC.)) CONFIDENTIAL FILED
Defendant/Counter-Plaintiff.) UNDER SEAL)

PLAINTIFF CRYOVAC INC.'S RESPONSIVE BRIEF IN OPPOSITION TO PECHINEY'S MOTION FOR SUMMARY JUDGMENT ON PATENT ISSUES

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I. NATURE AND STAGE OF PROCEEDINGS

In this action, plaintiff Cryovac, Inc. ("Cryovac") has asserted, *inter alia*, that defendant Pechiney Plastic Packaging, Inc.'s ("Pechiney") ClearShield™ product infringes claim 11 of U.S. Patent No. 4,755,419 ("the '419 patent," Ex. A).¹ Pechiney has moved, *inter alia*, for summary judgment on patent issues. Pursuant to paragraph 10 of the Scheduling Order (D.I. 22), Cryovac submits this responsive brief opposing Pechiney's Motion for Summary Judgment on Patent Issues (D.I. 195, 196). An affidavit by Dr. Garth Wilkes in support of Cryovac's opposition to Pechiney's motion is submitted herewith ("Wilkes Aff.") Relevant discovery has been completed and the issue of claim construction is before the Court. Also pending before the Court is Cryovac's related Motion to Exclude Expert Testimony Pursuant to Principles Announced in *Daubert* (D.I. 199), which moves to exclude opinions of Pechiney's expert Dr. Mount that Pechiney is relying on in its summary judgment motion.²

II. SUMMARY OF ARGUMENT

1. Summary judgment on no literal infringement must be denied because Pechiney applies an incorrect claim construction for the claim phrase "at least seven layers

¹ Citations to "Ex. __" in this responsive brief refer to exhibits found in the "Appendix of Exhibits Cited in the Affidavit of Garth L. Wilkes and Cryovac's Responsive Brief in Opposition to Pechiney's Motion for Summary Judgment on Patent Issues," which is submitted concurrently.

² Cryovac's Motion to Exclude involves, *inter alia*, an untimely "second supplemental expert report" by Dr. Mount filed on September 13, 2005, four weeks <u>after</u> the close of discovery. In that second supplemental report, Dr. Mount opines on the declarations of Drs. Gilbert and Dimas which Pechiney produced on the last day of discovery, August 19, 2005. (Ex. G, H.) Cryovac has moved to exclude Dr. Mount's opinions under *Fed. R. Evid.* 702 (because the opinions were not derived by the scientific method, are not objectively verifiable and will not assist the trier of fact); *Fed. R. Evid.* 703 (because the opinions rely on inadmissible hearsay that is not the type of data reasonably relied upon by experts in this field); and *Fed. R. Evid.* 403 (because of unfair prejudice to Cryovac and potential jury confusion). (D.I. 199.)

arranged symmetrically," which is contrary to the intrinsic record for the '419 patent and which improperly reads limitations into claim 11.

- Summary judgment on the doctrine of equivalents must be denied because the 2. doctrine of equivalents does not apply. Here there are no differences between ClearShield™ and what is claimed in claim 11. Rather, the claim as properly construed is literally infringed.
- Summary judgment on anticipation must be denied because Pechiney has not 3. proven by clear and convincing evidence that either the Gilbert Film or the Allied News Release Film C contains all the elements in claim 11, either directly or inherently. A reasonable jury could find that the uncorroborated, unreliable recollections of Dr. Gilbert and the unscientific, unverifiable opinions of Dr. Mount regarding the existence of the Gilbert Film and its properties did not prove clearly and convincingly that the Gilbert Film or the undated Allied News Release disclosed an oriented coextruded film with the layer structure set forth in claim 11.
- Summary judgment on obviousness must be denied because (1) the parties 4. have material factual disputes regarding several of the factual determinations outlined by the Supreme Court in Graham, (2) there was no motivation to orient either the Gilbert Film or the Allied News Release Film C, nor an expectation of success in doing so, given the disclosures in the prior art, and (3) there is compelling objective evidence showing non-obviousness, including
- Summary judgment on lack of enablement must be denied because Pechinev 5. has not provided any evidence (let alone clear and convincing evidence) that one of ordinary skill in the art would have been unable to make the films covered by claim 11 (based on the '419 specification and what was known in the art at the time the '419 application was filed) without undue experimentation.

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IV. STATEMENT OF MATERIAL FACTS

A. SHAH '419 PATENT

The '419 patent-in-suit describes and claims an oriented coextruded film having multiple layers arranged in a specified manner and made from specific materials. This film was invented by a Cryovac engineer named Gautam P. Shah. Mr. Shah made this invention by August 30, 1985. (Ex. F at 15:1-18:10.) A patent application was filed on March 21, 1986. (Ex. A.)

Mr. Shah's patent application includes a detailed description of how to make and use his invention. (Ex. A at col. 3, lns. 22-39, col. 4, ln. 47 - col. 9, ln. 4.) He included two specific examples of films that fell within his invention and provided a detailed description of the materials he used and processing conditions he employed to make those specific films. (Ex. A at col. 7, ln. 1 - col. 8, ln. 34.) He also provided teachings concerning how to make other films that fell within his invention including teachings concerning how to choose suitable polymer components that may be used together with guidance as to suitable layer thicknesses and important information concerning processing, including what temperature range to use and what conditions to use for orientation. (Ex. A at col. 4, ln. 60 - col. 6, ln. 64, col. 8, lns. 60-68.)

Based on this information provided in the '419 patent, Cryovac's technical expert, Dr. Garth L. Wilkes, has provided his expert opinion that the '419 patent enables a person of ordinary skill in this art to make and use the invention of claim 11 of the '419 patent without undue experimentation. (Wilkes Aff. ¶ 53-55; Ex. D at 16:14-19; 109:11-117:13.) Pechiney has not offered any contrary expert opinion. Nor did the patent Examiner ever raise any enablement concerns during the '419 patent's prosecution history.

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The U.S. Patent and Trademark Office ("PTO") issued Mr. Shah the '419 patent on July 5, 1988. (Ex. A.) The '419 patent's broadest claim is patent claim 11, which reads as follows:

> An oriented coextruded film having at least seven layers arranged symmetrically comprising:

- a core layer comprising an ethylene vinyl alcohol (a) copolymer³;
- two intermediate layers each comprising a polyamide4; (b)
- two outer layers each comprising a polymeric material (c) or blend of polymeric materials; and
- two layers, each comprising an adhesive polymeric (d) material, whichadhere each of said intermediate layers to a respective outer layer.

SHAH '419 PATENT WAS A DEPARTURE FROM THE PRIOR ART В.

The invention described in claim 11 of the '419 patent was a departure from the prior art. Prior art patents had taught away from attempting to orient EVOH- and nylon-containing multilayer films. (Wilkes Aff. ¶¶ 30-34.) The prior art also taught away from using nylon together with EVOH. (Wilkes Aff. ¶¶ 35-36.) In view of the known difficulties with orienting multilayer films containing EVOH and nylon, a person of ordinary skill would not have had a reasonable expectation of success that the '419 patent claim 11 film could be successfully oriented to achieve the desired film properties before Mr. Shah's invention thereof. (Wilkes Aff. ¶ 37.)

Pechiney argues that the invention of claim 11 of the '419 patent was anticipated by



("the Gilbert Film" or "Allied Film"5).

ne J. of Food Science article says that work in the article was "performed as a part

³ Ethylene vinyl alcohol copolymer is referred to herein as "EVOH."

 $^{^4}$ Nylon is a representative polyamide. (Wilkes Aff. \P 5, n. 1)

⁵ Dr. Gilbert claims

However, there is no reliable basis from which to conclude that this film was oriented.

(Wilkes Aff. ¶¶ 4-8.) Dr. Gilbert's

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which strongly indicates that this

film was unoriented. (Wilkes Aff. ¶ 5-8; Ex. L at Tables 1, 2, 4.) Moreover, Dr. Gilbert

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'(Wilkes Aff. ¶¶ 6-8.) Dr. Gilbert

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(Ex. G.) Moreover,

Pechiney blocked discovery regarding Dr. Gilbert on the ground he was serving as Pechiney's consultant. (Ex. U, ¶ 3.)

Nor is there a reliable basis to conclude that the Gilbert Film was co-extruded. (Wilkes Aff. ¶ 9-11.) Moreover, the actual structure and date of the Gilbert Film are not clearly shown by the materials relied on by Pechiney. (Wilkes Aff. ¶ 12-17.) For one thing, there is an inconsistency between the Gilbert Declaration, REDACTED and the Allied News Release, which describes a nine-layer structure. (Wilkes Aff. ¶ 12-13; Ex. G ¶ 9, 16; Ex. L at Tables 1, 2, 4.) Also, the time frame of the Gilbert Film is unclear. (Wilkes Aff. ¶ 14-17.) Indeed, the only dated document that refers to the seven-layer Gilbert Film is a 1987 publication, which is too late to qualify as prior art. (Wilkes Aff. ¶ 18.)

Pechiney also contends that film C described in the Allied News Release is anticipatory. However, the Allied News Release Film C is not disclosed to be oriented. (Wilkes Aff. ¶¶ 19-21.) In fact, none of the nylon-containing films in the Allied News Release are disclosed as being oriented, though, in contrast, one non-nylon containing film (Film F) is expressly disclosed as being oriented. (Wilkes Aff. ¶ 9; Ex. L.) In view of this express

of NJAES Project No. D-10533-1086 supported by the N.J. Agricultural Experimental Station," not Allied. (Ex. J at PPPI 008456.)

disclosure of another film as being oriented, the conclusion the reader draws from the Allied News Release is that Film C is not oriented. (Wilkes Aff. ¶ 19.) The structure of the Allied News Release Film C is even ambiguous. Pechiney argues it is a nine-layer film (P.S.J., p. 13)⁶ while Pechiney's expert states that the layer structure in the Allied News Release is "an obvious typographical or transcriptional error" and that it is really a seven-layer film with a different structure (Ex. I, Tab D at p. 4.) Also, the date of publication is not indicated in the Allied News Release. (Wilkes Aff. ¶ 19; Ex. L.) Furthermore, there is no enabling disclosure in the Allied News Release teaching how to orient the films described therein. (Wilkes Aff. ¶ 22.)

In view of the deficiencies in its anticipation defense, Pechiney also argues as a fall-back position that the invention described in claim 11 of the '419 patent would have been obvious. However, Pechiney's obviousness contention fails to consider the scope and content of the prior art in its entirety. (Wilkes Aff. ¶ 25.) Packaging film designs are not made in the abstract. Rather they are made with particular end uses, packing equipment and packaging product protection targets in mind. (Wilkes Aff. ¶ 26; Ex. I, Tab A at p. 4.)

It is also necessary to have actual experience with a product to understand its properties and failure mechanisms. (Wilkes Aff. ¶¶ 26-27.) Without actual testing, there would have been no reasonable expectation of success that changing the layers of a film, introducing new layers, or changing processing conditions could be successfully achieved or would result in a successful product. (Wilkes Aff. ¶27.) Indeed, the large number of packaging design considerations to be considered by one of ordinary skill in the art do not uniformly point to a single direction. (Wilkes Aff. ¶28; Ex. I, Tab A at pp. 7-8.) For example, including nylon layers in a packaging film can improve puncture resistance but at the expense of increasing

⁶ Citations to "P.S.J." in this responsive brief refer to Pechiney's "Memorandum in Support of Pechiney's Motion for Summary Judgment on Patent Issues." (D.I. 196.)

undesirable stiffness. *Id.* Thus, rather than taking factors in isolation, one skilled in the art would have needed to consider all the relevant factors, even though they may have pointed in opposite directions. This reality severely limited the scope of what modifications would have been obvious. (Wilkes Aff. ¶ 29; Ex. B ¶ 23.) Thus, it would not be obvious to orient all films based on disclosures in patents (such as the films in U.S. Patent Nos. 5,055,355⁷ (Ex. V) and 4,572,854⁸ (Ex. W)) of significantly different film structures with different layer arrangements containing different types and numbers of layers. (Wilkes Aff. ¶ 37; Ex. B ¶¶ 36-44.)

Considering the scope and content of the prior art in its entirety, it would not have been obvious to modify the Gilbert Film or Film C reported in the Allied News Release. (Wilkes Aff. ¶¶ 46-52.) A film's desirable barrier properties are a function of film thickness, with thinner films providing less desirable barrier properties compared to thicker but otherwise equivalent films. (Wilkes Aff. ¶ 48.) Orienting a film makes the film thinner, thus, reducing

Pechiney argues the '355 patent "disclosed a multilayer film having nylon/EVOH/nylon layers." (P.S.J., ¶ 13, 35, 36.) The patent column and lines Pechiney cites clearly only state that "[t]he film laminate of the present invention [has] at least one polyamide layer and at least one [EVOH] layer." (Ex. V at col. 4, lns. 57-64.) A film with one polyamide layer and one EVOH layer (or even a film containing nylon/EVOH/nylon) is obviously a very different structure from the allegedly nine-layer Allied News Release Film C, or the Shah '419 claim 11 film. (Ex. B ¶ 41, 62-63.) Based on the differences in film structure of the '355 films compared to the Gilbert Film or Allied News Release Film C, there would not have been an expectation of successfully orienting the latter films. (Wilkes Aff. ¶ 37; Ex. B ¶ 16.)

The '854 films did not contain intermediate nylon layers at all. (Ex. M at 110:5-9; Ex. B ¶ 121-123.) The prior art taught that it was difficult to orient nylon-containing films. (Wilkes Aff. ¶ 32-33, 37; Ex. B ¶ 127-128, 133.) Furthermore, the '854 patent teaches that "the existing sealable, multilayer films having a barrier layer comprised of [EVOH] cannot be produced by extruding all of the layers simultaneously to obtain an orientation of all layers by stretching under identical conditions." (Ex. W at col. 1, lns. 48-54, emphasis added.) Indeed, the prior art taught that EVOH-containing films were difficult to orient. (Wilkes Aff. ¶ 30-31, 34; Ex. B ¶ 38-44; Ex. D at 229:14-234:20.) Given the fact that there are no nylon intermediate layers in the '854 films and the known difficulties in orienting both EVOH- and nylon-containing films, there would have been no expectation of successfully orienting the Gilbert Film or the Allied News Release Film C--which Pechiney alleges are coextruded films containing both nylon and EVOH layers. (Wilkes Aff. ¶ 30-37; Ex. B ¶ 16, 121-133.)

the film's barrier properties. *Id.* For example, the stretch conditions successfully employed by Shah reduced film thickness by approximately ten times. (Wilkes Aff. ¶ 49; Ex. A at col. 7, lns. 27-34.) The Gilbert Film and Film C of the Allied News Release were already very thin. (Wilkes Aff. ¶ 49, 59.) Given the difficulty of orienting EVOH- and nylon-containing multilayer films reported in the prior art, one would not have been motivated to orient these films. (Wilkes Aff. ¶ 30-37, 48-50, 52.) Moreover, one would not have had a reasonable expectation that these films could be successfully oriented. *Id*.

Pechiney's obviousness contentions also fail to consider objective indicia of non-obviousness. (Wilkes Aff. ¶¶ 38-45.) For example,

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(Ex. R at PPPI 008164; Wilkes Aff. ¶ 39.) After this

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. (Id.) Pechiney's.

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' (Wilkes Aff. ¶ 40.) It is

both surprising and unexpected that

ffrom the time of

Shah's invention, this invention was still

REDACTED Apperior to alternatives. Id.

Furthermore, both Cryovac and Pechiney have sold commercially successful embodiments of claim 11 of the Shah '419 patent. (Wilkes Aff. ¶¶ 41-44; Ex. B ¶¶ 144-146.) Moreover, the commercial success of these embodiments is due to the merits of Shah's invention and its superiority over alternatives. (Wilkes Aff. ¶¶ 44-45; Ex. B ¶¶ 145-146.) Indeed,

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Ex. R at PPPI 008256; Wilkes Aff. ¶ 44.)

PECHINEY'S CLEARSHIELDTM PRODUCT C.

There is no dispute as to the structure of Pechiney's commercial ClearShieldTM ClearShield™ is an oriented, coextruded seven-layer product.9 film that is oriented by reheating the coextruded film to its orientation temperature and stretching it to realign the molecular configuration by a blown bubble process. (Wilkes Aff. the seven layers of ¶ 43; ClearShield™ are an EVOH-containing core layer, two intermediate polyamide (i.e., nylon) layers, two adhesive layers that adhere respective intermediate layers to outer polymeric layers and two outer polymeric layers. (Wilkes Aff. ¶ 43; Ex. M at-

the arrangement of the layers, i.e., that one nylon layer, REDACTEMOTEOVER, one adhesive layer and one outer polymeric layer are arranged in the same order on each of the opposite sides of the core layer in ClearShield TM . Id.

Pechiney contends that it is not infringing because ClearShield™ is not a symmetrical structure in that the outer polymeric layers include different amounts of one slip/antiblock additive and have different thicknesses. (P.S.J., pp. 21-23.) Pechiney's proposed claim construction is inconsistent with the '419 patent specification, which discloses that preferred embodiments of the invention can have outer layers having different thicknesses. (Ex. A at col. 5, lns. 40-45, "outer layers 16 and 18 preferably each comprise from about 20% to 40%... . of the total thickness of the multilayer film.") (emphasis added).) The '419 specification also

⁹ Pechiney claims that Pechiney's own analytical testing documents, nowever, & Ex. X at PPPI 003410.) Moreover, (Ex. Z at 20:7-21:5.) (Ex. Y at PPPI 006312.)

teaches the use of "small amounts of slip and antiblock additives." (Ex. A at col. 5, lns. 28-29, 36-40.)

Moreover,

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Even Pechiney's own expert, Dr. Mount, conceded that one of ordinary skill in the art when the '419 patent application was filed would have "absolutely" understood and used different amounts of slip and antiblock additives in the two outer layers. (Ex. M at 242:4-247:18; Ex. I, Tab A at p. 20.) Also, statements in the prior art (in patents identified by Dr. Mount as being relevant) teach that "The thickness of each layer [in a multilayer film] is not particularly critical." (Ex. AA at col. 7, lns. 26-27; see also Ex. W at col. 5, lns. 45-47.)¹⁰ Moreover.



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(Ex. BB at PPPI 013933, emphasis added.) He

(Ex. BB at PPPI 013932.)

III. ARGUMENT

A. SUMMARY JUDGMENT AND INVALIDITY STANDARDS

Summary judgment is only appropriate on an issue if there are no genuine issues of material fact, and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). "The moving party bears the burden of proving that no genuine issue of material fact

¹⁰ The '854 patent, cited throughout Pechiney's summary judgment brief, states: "The [multilayer, coextruded] film is preferably sealable, while the sealable layers on either side of barrier layer D may have different thicknesses and compositions." (Ex. W at col. 5, lns. 45-47.)

exists." Izumi Prods. Co. v. Koninklijke Philips Elecs. N.V., 315 F. Supp.2d 589, 597 (D. Del. 2004), aff'd, 140 F. App'x. 236 (Fed. Cir. 2005). The court must view the underlying facts (and all reasonable inferences therefrom) in the light most favorable to the party opposing the motion. Id. The Judge's function is not to weigh the evidence, but to determine whether there is a genuine factual issue for trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986).

All U.S. patents are presumed valid. 35 U.S.C. § 282. This presumption of validity is "never annihilated, destroyed, or even weakened, regardless of what facts are of record." ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1574-75 (Fed. Cir. 1984) (emphasis in original). On summary judgment, the moving party has the burden of proving invalidity by "clear and convincing evidence based on undisputed facts." Quad Envil. Techs. Corp. v. Union Sanitary Dist., 946 F.2d 870, 872 (Fed. Cir. 1991).

B. LITERAL INFRINGEMENT

The first step in an infringement analysis requires that the asserted claim be interpreted based on the intrinsic evidence, the claims themselves, the patent specification, and the prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315-17 (Fed. Cir. 2005) (en banc). In doing so, it is improper to read additional limitations into the claim from the specification. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999).

Pechiney's request for summary judgment of no literal infringement is based entirely on its construction of the claim phrase "at least seven layers arranged symmetrically." (P.S.J., pp. 20-24.) Pechiney argues that under its proposed definition of layers "arranged

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¹¹ "Facts that could alter the outcome are 'material,' and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." *Horowitz v. Fed. Kemper Life Assurance Co.*, 57 F.3d 300, 302 n.1 (3d Cir. 1995) (citations omitted).

symmetrically," ClearShield™ does not literally infringe claim 11 because (1) ClearShield's two outer layers are not of equal thickness (

However, Pechiney's proposed construction of this claim term is incorrect as a matter of law. Pechiney improperly reads additional requirements into claim 11 which are unsupported and contradictory to the intrinsic evidence, which should be relied upon to interpret the claim. (Cryovac's Initial Brief on Claim Construction, D.I. 203, pp. 8-10, 24-31; Johnson, 175 F.3d at 989.)

Shah's '419 patent specification teaches that each layer in a pair of corresponding layers (e.g., the two outer polymeric layers) may vary independently in thickness. That is, the outer layers in the '419 films "preferably each comprise from about 20% to about 40%...of the total thickness of the multilayer film" (Ex. A at col. 5, lns. 42-45, emphasis added); the two adhesive layers "each comprise from about 5% to about 15% of the total thickness of the multilayer film" (Ex. A at col. 6, Ins. 65-67, emphasis added); and for the intermediate polyamide layers "each layer can form between 5% and 25% of the total thickness of the multilayer film" (Ex. A at col. 5, lns. 20-22, emphasis added). Thus, rather than teach that the film must have absolute geometric symmetry (as Pechiney proposes), the '419 patent teaches that corresponding layers do not need to be the same thickness.

Reading in an "absolute symmetry" limitation requiring mirror image compositions also would be inconsistent with the intrinsic record and other elements of the claim.

(P.S.J., p. 23.) If you raise the percentage of one component in a mixture, the percentage of other components is automatically decreased. Hence, there are really no "other differences" at all.

¹² Pechiney also states that the outer layers

Consistent with the specification and the claim term "comprising," subparagraphs (b), (c) and (d) of claim 11 require the layer pairs to have a common recited component (e.g., the same polymeric component in both layers (c)) but each may contain additional components as well. Genentech Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997) ("Comprising' is a term of art used in [patent] claim language which means that the named elements are essential, but other elements, may be added and still form a [product] within the scope of the claim.") Thus, each layer may contain different types or amounts of additional components. The additional components expressly identified in the specification include, for example, slip and antiblock additives in the outer layers. (Ex. A at col. 5, lns. 29-30.)

In fact, as explained by Pechiney's own expert Dr. Mount, at the time the application for the Shah '419 patent was filed, one of ordinary skill in the art would have already known and understood that the two outer layers of a multilayer film will generally have different levels of slip and antiblock additives to provide the different properties necessary for processing. (Ex. M at 242:4 - 245:12 (referring to the outer layers as an "inner" and "outer" surfaces).) Thus, even without the disclosure in the specification, one of ordinary skill in the art would have already understood that layer pairs may, and in some cases must, differ in terms of composition, particularly with respect to slip and antiblock agents. S3, Inc. v. Nvidia Corp., 259 F.3d 1364, 1371 (Fed. Cir. 2001) ("The law is clear that patent documents need not include subject matter that is known in the field of the invention and is in the prior art, for patents are written for persons experienced in the field of the invention. To hold otherwise would require that every patent document to include a technical treatise for the unskilled reader") (citations omitted).

The discussion in the background section of the Shah '419 patent further demonstrates that no importance was placed upon or implied concerning the thicknesses, or compositional identity of layer pairs. In discussing eleven different prior art references, not once were the

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subjects of layer thickness, or compositional identity raised as being important or even relevant. (Ex. A at col. 1, ln. 48 - col. 3, ln. 5.) Rather, the issues addressed are the general compositions and ordering of the layers. Id. For example, the Shah '419 patent specification describes the import of U.S. Patent No. 4,514,465 to Schoenberg as disclosing a five-layer thermoplastic film having surface layers comprising a blend of four classes of components, without reference to Schoenberg's teachings that the two surface layers may contain different specific components within each of the four classes. (Ex. A at col. 2, Ins. 10-15; Ex. CC at col. 16. lns. 29-44.)

The prosecution history also lacks any clear disclaimer from which to read-in a narrowing construction of "arranged symmetrically." Indeed, layer thickness and compositional identity were never raised during prosecution, including when the rejections based on Sheptak and Mueller were addressed. Rather, Sheptak was distinguished because it "only teaches five layers, symmetrically arranged (14) and the overall eight layer structure (S) of the reference is asymmetric," without regard to the thickness or precise composition of any layer. (Ex. DD at CR0056-000155; Ex. HH at Fig. 1.)

Instead of a disclaimer, the prosecution history evidences that the claims were clarified to delete a limitation in the body of the claim stating "said layers of the multilayer films forming a symmetrical heat-shrinkable structure." (Ex. DD at CR0056-000152-53.) At the same time, the preamble was amended to include the present phrase "at least seven layers arranged symmetrically." (Id.) This amendment clarifies the claim to avoid any requirement for absolute symmetry or identity in opposing layers. (Ex. DD at CR0056-000155; Ex. EE at 126:2-128:3.) And again, rather than distinguishing the claims based on thickness or identity of compositions, the amendment to claim 11 that added the clause "at least some layers arranged symmetrically" was explained as clarifying that "(1) at least seven layers are claimed, and that (2) these layers are symmetrically arranged." (Ex. DD at CR0056-000155.)

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Even the prior art analysis of Pechiney's expert, Dr. Mount, is inconsistent with defining "arranged symmetrically" to require "absolute symmetry." For example, Dr. Mount opined that U.S. Patent 4,511,610 to Yazaki discloses seven-layer structures having layers "arranged symmetrically." (Ex. I, Tab A at p. 26.) However, as Dr. Mount admits, Yazaki expressly states "[t]he thickness of each layer is not particularly critical in the multi-layer vessel." (Ex. AA at col. 7, lns. 26-27; Ex. M at 76:9-77:4.) Similarly, citing the compositions of the layers and a figure in the '854 patent, Dr. Mount alleges that the '854 patent discloses layers "arranged symmetrically." (Ex. I, Tab A at p. 28.) However, the '854 patent also allows the outer layers to have different thicknesses and compositions. (Ex. W at col. 5, lns. 45-47.)

Thus, in defining layers "arranged symmetrically" in claim 11 to require that all corresponding layers must have the same thickness and same composition (including the same % of slip/antiblock additives), Pechiney is reading limitations into claim 11 which are contrary to the teachings in the patent specification and prosecution history, making the patent's preferred embodiments unworkable¹³, and contrary to what one of ordinary skill would have understood when reading the patent. This is simply not allowed. *See Phillips*, 415 F.3d at 1313; *Johnson*, 175 F.3d at 989; *Chimie*, 402 F.3d at 1377.

Because Pechiney applies an incorrect, untenable definition of the claim term in its infringement analysis, it cannot win summary judgment of literal infringement as a matter of

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understood that it was a logical impossibility for corresponding layers to always be the same thickness and still be able to practice Shah's preferred embodiments. For example, the specification states the outer layers are each preferably about 20% to about 40% of the total thickness of the film. (Ex. A at col. 5, lns. 42-45.) If, as Pechiney argues, the two outer layers need to be the same thickness, then using the maximum thickness for each outer layer would use up 80% of the total film thickness, and only leave 20% for the other 5 layers-making it impossible for the adhesive layers, the nylon layers, and the EVOH core to fall within their "preferred" ranges. (Ex. A at col. 6, lns. 65-67; col. 5, lns. 20-22; D.I. 203, p. 27); see Chimie v. PPG Indus. Inc., 402 F.3d 1371, 1377 (Fed. Cir. 2005) (district court properly rejected accused infringer's proposed construction of a claim term because that construction would not read on a preferred embodiment).

C. DOCTRINE OF EQUIVALENTS DOES NOT APPLY

In the present case, the Court should accept Cryovac's proposed definition of "at least seven layers arranged symmetrically." Accepting that definition, then there are no differences between ClearShieldTM and what is claimed in claim 11 and therefore the doctrine of equivalents does not apply. Rather, the claim, as properly construed, is literally infringed.

D. ANTICIPATION

- Pechiney's reliance on uncorroborated, unreliable evidence precludes summary judgment because a jury could find the evidence unpersuasive to show anticipation.
 - Law on uncorroborated oral testimony used to show anticipation or invalidity.

Pechiney argues in its summary judgment brief that claim 11 of the '419 patent is invalid as anticipated, alleging that two films (the Gilbert Film and the Allied News Release Film C) were used or disclosed more than one year prior to the filing of the '419 patent application. (P.S.J., pp. 29, 31.) No documentary evidence shows that those two films contained all the claim 11 limitations, so Pechiney relies on the Declaration of Dr. Gilbert (and Dr. Mount's untimely and unscientific reliance on Dr. Gilbert's Declaration) as "proof" of the composition, structure, and properties of two films. (P.S.J., pp. 12, 29-33.) Dr. Gilbert and Dr. Mount's testimony, however, is precisely the type of uncorroborated, unverifiable, unreliable recollection testimony that the Supreme Court and Federal Circuit have held cannot provide grounds for invalidating a patent under § 102.

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"The law has long looked with disfavor upon invalidating patents on the basis of mere testimonial evidence absent other evidence that corroborates that testimony." Finnigan Corp. v. ITC, 180 F.3d 1354, 1366 (Fed. Cir. 1999). The Supreme Court recognized that such evidence is "unsatisfactory" due to "the forgetfulness of witnesses, their liability to mistakes, [and] their proneness to recollect things as the party calling them would have them recollect them." Washburn & Moen Mfg. Co. v. Beat 'Em All Barbed-Wire Co., 143 U.S. 275, 284 (1892).

"The Supreme Court's view of human nature as well as human recollection, whether deemed cynical or realistic, retains its cogency" even 100 years later. Woodland Trust v. Flowertree Nursery Inc., 148 F.3d 1368, 1373 (Fed. Cir. 1998). "This view is reinforced, in modern times, by the ubiquitous paper trail of virtually all commercial activity." Id. "It is rare indeed that some physical record (e.g., a written document such as notes, letters, invoices, notebooks, or a sketch or drawing or photograph showing the device, a model, or some other contemporaneous record) does not exist." 1d. Accordingly, "[c]orroboration of oral evidence of prior invention is the general rule in patent disputes." Id. at 1371. Without corroboration, such testimonial evidence "is insufficient as a matter of law to establish invalidity" of a patent because "such testimony alone cannot surmount the hurdle that the clear and convincing evidence standard imposes in proving patent invalidity." Finnigan, 180 F.3d at 1370.

Moreover, "summary judgment is not appropriate where the opposing party offers specific facts that call into question the credibility of the movants witnesses." Typeright Keyboard Corp. v. Microsoft Corp., 374 F.3d 1151, 1158-59 (Fed. Cir. 2004) ("Typeright pointed to specific facts that tend to discredit the testimony of [Microsoft's experts]. These facts create a genuine issue as to the credibility of Microsofts witnesses. . . . In such

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¹⁴ Corroboration is necessary even when the witness is not himself an interested party, but simply testifying on behalf of an interested party. Finnigan, 180 F.3d at 1367.

circumstances, '[t]he court may not assess the credibility of testimony when granting summary judgment." (citations omitted)).

> Neither Dr. Gilbert's uncorroborated testimony, nor b) Dr. Mount's reliance on that testimony, can prove anticipation.

In this case, Pechiney submitted a short Declaration by its consulting expert Dr. Gilbert, REDACTED

(Ex. G.) However, Dr. Gilbert's

testimony about the characteristics of the Gilbert Film,

Is not corroborated and is therefore unreliable to show anticipation. See Finnigan, 180 F.3d at 1366; Woodland Trust, 148 F.3d at 1371-73. In fact, the REDACTED
(Ex. L at Tables 1, 2, 4; Ex. G ¶ 16, 18; contemporaneous Allied News Release,

Wilkes Aff. § 5.) Additionally, despite the fact that Dr. Gilbert's work was supposedly performed in a laboratory or research facility by scientists at the request of another company,



Evidence that the Federal Circuit in Woodland Trust and Finnigan indicated should exist. (Wilkes Aff. ¶¶ 7-8; Ex. G; see Woodland Trust, 148 F.3d at 1373; Finnigan, 180 F.3d at 1366 ("Mere testimony concerning invalidating activities is received with further skepticism because such activities are normally documented by tangible evidence such as devices, schematics, or other materials that typically accompany the inventive process.").)

Thus, a reasonable jury could agree (or the Court could find as a matter of law) that the Supreme Court and Federal Circuit properly assessed this kind of uncorroborated testimony and find that it was unreliable and insufficient to invalidate a patent. See Washburn, 143 U.S. at 284; Finnigan, 180 F.3d at 1366, 1370; Woodland Trust, 148 F.3d at 1371-73. Since a jury could conclude that Dr. Gilbert's recollections are not clear and convincing evidence proving

the characteristics of the Gilbert Film, summary judgment on anticipation should be denied for this reason in and of itself.

As for <u>Dr. Mount's</u> testimony relying on Dr. Gilbert's memory (assuming the jury hears Dr. Mount's opinion on the subject at all), ¹⁵ a reasonable jury could <u>certainly</u> find that Dr. Gilbert's unreliable testimony does not suddenly become more reliable simply because Dr. Mount repeated it. Chemipal Ltd. v. Slim-fast Nutritional Foods Int'l, Inc., 350 F. Supp. 2d 582, 588 (D. Del. 2004), quoting S.E.C. v. Lipson, 46 F. Supp. 2d 758, 763 (N.D. Ill. 1998).

Dr. Mount did not review or analyze any data, but simply accepted Dr. Gilbert's REDACTED

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shortcomings, a reasonable jury could decide that Dr. Mount's unverifiable opinions were not persuasive expert testimony and did not "surmount the hurdle that the clear and convincing evidence standard imposes in proving patent invalidity." *Finnigan*, 180 F.3d at 1370. Indeed, a reasonable jury could conclude (as the Third Circuit did in *TMI* when an expert did not rely on actual data or samples in reaching his opinion), that "[c]ommon sense alone suggests that such evidence is 'based on an unreliable source of information." *In re TMI Litig.*, 193 F.3d 613, 698 (3d Cir. 1999) (citation omitted).

Because a jury could find for Cryovac, given Pechiney's "heavy burden when establishing prior public knowledge and use based on long-past events" and given the dubious evidence presented by Pechiney through both Dr. Gilbert and Dr. Mount, summary judgment

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on Dr. Gilbert's recollections, on the grounds that such opinions are inadmissible under: Fed. R. Evid. 702 (because Dr. Mount's opinions were not derived by the scientific method, are not objectively verifiable and will not assist the trier of fact); Fed. R. Evid. 703 (because Dr. Mount's opinions rely on inadmissible hearsay that is not the type of data reasonably relied upon by experts in Dr. Mount's field); and Fed. R. Evid. 403 (because of unfair prejudice to Cryovac and potential jury confusion). (D.I. 199, pp. 16-21.)

should be denied. Woodland Trust, 148 F.3d at 1373. Summary judgment is also "not appropriate" for the additional reason that Cryovac has offered facts that "call into question the credibility of the movant's witnesses." Typeright, 374 F.3d at 1158.

> Even if the Court were to admit Gilbert's uncorroborated 2. memories and Mount's unscientific and untimely opinions into evidence, it would not establish anticipation.

To invalidate a claim by anticipation, a single prior art reference (or object in public use) must contain every limitation in the asserted claim; the reference "must describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art." Verve, LLC v. Crane Cams, Inc., 311 F.3d 1116, 1120 (Fed. Cir. 2002). The question of what a reference teaches and whether it discloses every element of a claim is a question of fact that should be left to the jury. Med. Instrumentation & Diagnostic Corp. v. Elekta AB, 344 F.3d 1205, 1221 (Fed. Cir. 2003).

For a missing element to be "inherent" in a prior art reference (or object), the moving party must show by clear and convincing evidence that the undisclosed subject matter was "necessarily present" or a "'natural result flowing from' the explicit disclosure of the prior art." Cont'l Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991); Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1379 (Fed. Cir. 2003) (citations omitted). Inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." Cont'l Can, 948 F.2d at 1269 (emphasis in original) (citation omitted).

Pechiney argues that claim 11 of the '419 patent is invalid as anticipated under § 102(b) based on an alleged public use of the Gilbert Film that Pechiney asserts contained all

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a) No reliable evidence that the Gilbert Film was oriented.

There is no reliable evidence that the Gilbert Film was oriented. (Wilkes Aff. ¶ 5-8.) In fact, no publications indicate the Gilbert Film was an oriented film, so Pechiney argues the Gilbert Film was "inherently" oriented. (P.S.J., pp. 30-31.) Pechiney only points to Dr. Gilbert's unverifiable, uncorroborated "Film was "inherently" oriented.



and Dr. Mount's reliance on

Dr. Gilbert's memory. 18 (P.S.J., p. 31; Ex. G ¶ 16-18.) Significantly,



¹⁶ The Court does not need to consider Pechiney's anticipation arguments at all if the Court adopts Cryovac's proposed definition of "oriented," based on the explicit definition of that term in the '419 specification. Pechiney only argues that the two films anticipate claim 11 "[ilf the Court construes the claim term 'oriented' as proposed by Pechiney." (P.S.J., p. 28.)

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¹⁷ The Allied News Release, the *Journal of Food Science* article, and the *Journal of Commerce* article. (P.S.J., 12; Ex. G at ¶ 9.)

¹⁸ Since the data which supposedly showed orientation is apparently not available to anyone, we have no way of knowing what the data actually does show. Also, Pechiney claims

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(Wilkes Aff. ¶¶ 6-8.)

However,

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(Wilkes Aff. ¶ 6-7.) Before concluding whether the Gilbert Film was oriented, one would also need to know at least the sample's history, handling conditions, and the test methodology used for the analysis, especially since there is no data to support any of Dr. Gilbert's memories. (Wilkes Aff. ¶ 7-8.) Pechiney's expert Dr. Mount then simply relies on Dr. Gilbert's recollection without seeing any data to opine that the Gilbert Film is oriented—an unscientific and unacceptable way to arrive at an "expert opinion." See Daubert v. Merrell Dow Pharm., 509 U.S. 579, 589 (1993); 19 Ex. I ¶ 19-22, Tab D at pp. 4-6.20

Thus, Pechiney did not prove by clear and convincing evidence that the Gilbert Film was necessarily "oriented," as oriented is specifically defined in the '419 patent, and summary

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Dr. Kimmel agrees that the Instron (i.e., a stress/strain-type test) and cross polarization tests themselves are reliable indicators of orientation. (P.S.J., 31.) In reality, Dr. Kimmel never discussed cross polarization-type tests at his deposition at all, and Dr. Kimmel's testimony makes clear that one would need to see the results of any stress/strain-type tests in order to make any determinations about whether there was any orientation and if so how it was achieved. (Ex. FF at 64:21-67:20, 25:3-34:15.) Nor did Dr. Kimmel know or assess the results of such tests,

¹⁹ See also Pharmastem Therapeutics, Inc. v. Viacell Inc., No. 02-148-GMS, 2004 WL 2127192, at *11 (D. Del. Sept 15, 2004) (error to permit expert testimony where the expert "did not review or analyze any of the...samples in reaching her opinion" because such opinions "are not based upon any methods or procedures of science in general and certainly not upon her specific expertise as a stem cell biologist."); Chemipal, 350 F. Supp. at 594 (excluding expert's opinion where the expert had not verified the accuracy of the data upon which he based his opinion and because the opinion was "simply not objectively verifiable.")

²⁰ Mount says that "the Instron Tester and Cross Polarization test are appropriate tests to determine the presence of film orientation," and therefore the Gilbert Film (also known as Film C in the *Journal of Food Science* article) is oriented. (Ex. I, Tab D at p. 5.) However, Dr. Mount never saw the data from those tests that someone allegedly performed, and has no evidence of how those tests were used specifically on the <u>Gilbert Film</u>.

judgment on anticipation by the Gilbert Film should be denied. See Cont'l Can, 948 F.2d at 1269.

No reliable evidence that the Gilbert Film was coextruded. b)

Pechinev claims the Gilbert Film has the layer structure: HDPE/tie/nylon/EVOH/nylon/tie/HDPE and that it was "coextruded." (P.S.J., p. 29.) REDACTED Mr. Gilbert does not claim to remember that. CEDACTED

(Ex. G ¶ 10.) However, the Allied News Release does not disclose a

film with that layer structure. (Wilkes Aff. ¶ 9; Ex. L.) Neither does the Journal of Commerce article. (Ex. K; Wilkes Aff. ¶ 11.) The 1987 Journal of Food Science article is the only reference that refers to the seven-layer Gilbert Film, but (1) that reference cannot establish that the Gilbert Film is prior art because the reference is dated after Mr. Shah had made his invention and filed his patent application, (2) that reference only identifies non-nylon containing films as being oriented, and (3) that reference does not report any coextruded films. (Wilkes Aff. ¶ 5, 14, 18; Ex. J at PPPI 008454 (Film E).) It only discloses some film "laminates," which are not necessarily coextruded films. (Wilkes Aff. ¶ 10; Ex. J at PPPI 008456.) To prove inherent anticipation, however, Pechiney must show any missing elements were "necessarily present"--which Pechiney has obviously not shown. Cont'l Can, 948 F.2d at 1268; Wilkes Aff. ¶ 10.

Thus, a jury could find that Pechiney did not prove by clear and convincing evidence that the Allied Film was necessarily "coextruded"--an element in claim 11--and thus that the Allied Film did not anticipate claim 11.

Given that Pechiney relies on the uncorroborated recollection testimony of Dr. Gilbert to characterize the Gilbert Film, and that Pechiney has not established that the Gilbert Film was coextruded film, a reasonable jury could certainly find that Pechiney has not shown by

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"clear and convincing evidence" that the Gilbert Film contained every element in claim 11 of the '419 patent. Thus, Pechiney is not entitled to summary judgment on anticipation by the Gilbert Film even if the Court were to consider the Gilbert uncorroborated declaration and Dr. Mount's untimely and unscientific opinions based thereon.

3. The Allied News Release Film C

Pechiney also argues that the undated Allied News Release describes a film ("Allied News Release Film C") containing all the limitations of claim 11.^{21,22} (P.S.J., pp. 31-33.)

a) The Allied News Release Film C is not oriented.

The Allied News Release Film C in the News Release was not an "oriented" film under either party's definition of that term. Only one film is indicated as being oriented in the Allied News Release, and it is not Film C. (Wilkes ¶ 19-20; Ex. L at Tables 1, 2, 4.) Pechiney simply assumes (contrary to the publication Pechiney is relying on) that the Allied News Release Film C is inherently oriented because "[t]here is nothing disclosed that would indicate that it was unoriented" and "it would be extremely difficult to make a nine-layer film having a thickness of only 1.40 mils without orienting it." (P.S.J., p. 33; Wilkes Aff. ¶ 20-21; Ex. I, Tab A at p. 31.) Pechiney's own technical expert claimed in his second supplemental expert report that it was clear the Allied News Release Film C was not a nine-layer film, but in fact was a seven-layer film. (Ex. I, Tab D at p. 4.) Further, Pechiney fails to provide any scientific explanation as to why it would be difficult. (P.S.J., p. 33; Ex. I ¶ 21, Tab A at p. 31.)

²¹ Pechiney states that "ANR Film C is prior art under 35 U.S.C. § 102(a) because it was presented at a conference..." (P.S.J., p. 31.) However, since there is absolutely no evidence that a physical sample of the film was "presented at a conference," (i.e., a public use) Cryovac assumes Pechiney is arguing that the disclosure of the ANR Film C in the Allied News Release was the anticipatory disclosure.

²² Elsewhere, Pechiney and Dr. Mount have referred to the "ANR Film C" as the "Hatley film" and the Allied News Release as "the Hatley article."

Cryovac's expert, on the other hand, offers testimony that one can <u>not</u> assume that the Allied News Release Film C was oriented based on the vague and unsubstantiated claims offered by Pechiney. (Wilkes Aff. ¶¶ 19-21.) Contrary to Dr. Mount's assumptions, Dr. Wilkes states it would have actually been easier to make the Allied News Release Film C <u>un</u>oriented, given that orientation as defined in the '419 patent requires the additional processing steps of heating and stretching to realign the molecular configuration by a racking or blown bubble process. (Wilkes Aff. ¶21.) In fact, Pechiney offers <u>no</u> proof from any witness or documents that the Film C was oriented <u>as specifically defined in the '419 patent</u>.

Given that Pechiney's <u>only</u> evidence that the ANR Film C is inherently or "necessarily" oriented is its expert's unexplained assumption that it would be "difficult" to make the Film C <u>un</u>oriented, the jury could find that this was unpersuasive testimony conflicting with the document on which Pechiney is relying and with Cryovac's expert's testimony. Therefore, summary judgment should not be granted for this additional reason.

b) The Allied News Release is not dated.

To be an anticipating publication under 35 U.S.C. $102(a)^{23}$, Pechiney must show that the Allied News Release was published "before the invention thereof by applicant." (Ex. F at 17:17-18:10.) However, the Allied News Release itself is not dated, and the only evidence Pechiney has offered to establish a date of publication is its technical expert's statements that (1) the copy he received from his attorneys' offices was "bound," and (2) that it seemed two copies of the Allied News Release (also referred to as the Hatley article) were inserted into the conference proceedings some time before binding. (Ex. I, Tab D at pp. 2, 7-8; Wilkes Aff. 12; Ex. II at PPPI 008492-008505, PPPI 008597; Ex. M at 315:4-320:13.) Furthermore, the

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²³ 35 U.S.C. § 102(a) provides: "A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent".

copy of the conference proceedings provided by Pechiney in its summary judgment appendix and allegedly used by Pechiney's expert Dr. Mount, shows a date stamp "received April 2, 1986." (Pechiney Unified Appendix Ex. 16 at PPPI 008461; see also Ex. II at PPPI 008461.) This is after the invention was made (August 30, 1985) and after the filing date of Shah's patent application (March 21, 1986); therefore this proffered version of the conference materials cannot serve as an anticipating reference under § 102.

Pechiney contends that the publication date of the Allied News Release is September 5-6, 1985--the date of the conference. (P.S.J., p. 13.) However, Pechiney's expert Dr. Mount agreed at his deposition that the copy of the conference proceedings included a slipsheet where the News Release should have appeared; the slipsheet indicated that the News Release was not available yet. (Ex. II at PPPI 008468, PPPI 008596-97; Ex. M at 170:8-171:20, 315:4-320:13.) In any event, Pechiney's alleged publication date (September 5-6, 1985) is after Mr. Shah's invention date (August 30, 1985). Therefore, the Allied News Release is not prior art. 35 U.S.C. § 102(a). At the very least, a jury could decide that Pechiney has not presented "clear and convincing evidence" of an actual publication before the invention date, and therefore that the Allied News Release could not be an anticipating publication--thus precluding summary judgment. "Summary judgment in favor of the party with the burden of persuasion shere, Pechiney]...is inappropriate when the evidence is susceptible of different interpretations or inferences by the trier of fact." Oney v. Ratliff, 182 F.3d 893, 895 (Fed. Cir. 1999), quoting Hunt v. Cromartie, 526 U.S. 541, 553 (1999).

The structure of the Allied News c) Release Film C is ambiguous.

Pechiney claims that the Allied News Release Film C is a "nine-layer film" with the structure: HDPE/TIE/NYLON/TIE/EVOH/TIE/NYLON/TIE/HDPE. (P.S.J., pp. 13, 31.) Pechiney's expert Dr. Mount, however, declares in his second supplemental expert report that

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this Film C (what Mount calls the Hatley film) is actually a seven-layer film, and that the ninelayer structure presented in the News Release is "an obvious typographical or transcription mistake." (Ex. I, Tab D at pp. 4, 6.) If nothing else, this conflicting testimony shows that it is not clear what the Allied News Release Film C film structure is. (Wilkes Aff. ¶¶ 12-13; Ex. I, Tab D at p. 6.) An ambiguous reference cannot be an anticipatory reference because it cannot satisfy the clear and convincing evidence standard for proving invalidity. Finnigan, 180 F.3d at 1365; In re Hughes, 345 F.2d 184, 188 (C.C.P.A. 1965). Furthermore, "[i]t is important to note that it is not the 'task of the district court, to attempt to interpret confusing or general testimony to determine whether a case of invalidity has been made out, particularly at the summary judgment stage." eSpeed, Inc. v. Brokertec USA, L.L.C., 342 F. Supp.2d 244, 254 (D. Del. 2004), citing Schumer v. Lab. Computer Sys., 308 F.3d 1304, 1316 (Fed. Cir. 2002).

The Allied News Release does not contain d) an enabling disclosure.

Finally, a prior art reference cannot anticipate a claim unless the moving party establishes that the reference also contains an explanation of how to make and use the claimed invention, i.e., an "enabling disclosure." Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1354 (Fed. Cir. 2003). Here, there is no enabling disclosure in the Allied News Release as to how to orient the films described therein. (Wilkes Aff. ¶ 22.) This was confirmed by Pechiney's expert as well. (Ex. M at 183:9-13.) Since Pechiney did not meet its burden to show by clear and convincing evidence that the Allied News Release contained a disclosure which would enable a person to make the claimed invention with all the claim limitations in claim 11 (including orientation as defined in the '419 patent), the Allied News Release does not contain an enabling disclosure and cannot anticipate claim 11. See Amgen, 314 F.3d at 1354. Therefore, summary judgment of anticipation should be denied for this additional reason.

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Given that (1) the Allied News Release itself is not dated and Pechiney has not proven a publication date before Shah's invention, (2) the only evidence of the Allied News Release Film C film structure was described as a "typographical or transcriptional error" (according to Pechiney's expert), (3) the Allied News Release itself indicates that the Film C was not oriented, and (4) the Allied News Release does not contain the requisite enabling disclosure, a reasonable jury could certainly find that Pechiney has not proven by clear and convincing evidence that the Allied News Release disclosed every claim limitation in an enabling disclosure published before Shah's invention. Therefore, summary judgment of anticipation by the Allied News Release Film C must be denied. See Matsushita Elec. Indus. Co., Ltd. v. Cinram Int'l, Inc., 299 F. Supp.2d 348, 362 (D. Del. 2004) ("On the basis of th[e] conflicting evidence, the court believes that the issue of anticipation is both extremely complex and intensely fact specific. The court concludes that granting summary judgment would be premature and not based upon the most complete possible record.").

E. OBVIOUSNESS

"When the issue is patent invalidity due to obviousness, 35 U.S.C. § 103, the movant must overcome the statutory presumption of validity, 35 U.S.C. § 282, by proving obviousness by clear and convincing evidence based on undisputed facts. [24] All factual inferences must be drawn in favor of the opponent of the motion." *Quad Envtl.*, 946 F.2d at 872; see also McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1349 (Fed. Cir. 2001).

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²⁴ This "strong presumption of validity attaches to a patent after issuance <u>even in the face of evidence 'that was not before the PTO' during prosecution</u> of the patent." *ADE Corp. v. KLA-Tencor Corp.*, 220 F. Supp.2d 303, 340 (D. Del. 2002), citing Applied Materials, Inc. v. Adv. Semiconductor Materials of Am., 98 F.3d 1563, 1569 (Fed. Cir. 1996) (emphasis added).

1. Factual disputes regarding Graham factors

The Supreme Court has held that obviousness is a question of law based on numerous factual determinations which must all be considered by the trial court: (1) the scope and content of the prior art; (2) the differences between the claim and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) objective indications of nonobviousness (secondary considerations). Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966); Ruiz v. A.B. Chance, Co., 234 F.3d 654, 662-63 (Fed. Cir. 2000) ("Our precedent clearly established that the district court must make Graham findings before invalidating a patent for obviousness"). Genuine issues of material fact relating to these Graham factors preclude summary judgment on obviousness. Rockwell Int'l. Corp. v. U.S., 147 F.3d 1358, 1366-67 (Fed. Cir. 1998).

In this case, Cryovac and Pechiney dispute material facts relevant to the Graham factors. Both parties submitted several lengthy, detailed expert reports from technical experts regarding their opinions on the scope and content of the prior art (factor 1), as well as the differences between claim 11 and the prior art cited by Pechiney (factor 2). (Wilkes Aff. ¶ 1; Ex. B (Expert Report of Dr. Garth L. Wilkes); Ex. C (Rebuttal and Supplemental Report of Garth Wilkes); Ex. I ¶ 6, Tab A (Expert Report of Eldridge M. Mount III), Tab B (Rebuttal Expert Report Prepared by Dr. Eldridge M. Mount III) at pp. 21-25, and Tab D (Second Supplemental Expert Report of Eldridge M. Mount III); D.I. 203, Exhibit 6 (Cryovac's Rule 26(a)(2) Rebuttal Expert Report of Dr. Robert Kimmel).) Cryovac's expert Dr. Wilkes has also presented a lengthy declaration incorporating the opinions expressed in his expert reports and containing a detailed factual analysis controverting Dr. Mount's conclusion that the references Pechiney cites either contain or suggest combining all the claim limitations in claim 11. (Wilkes Aff. ¶¶ 23-52; Ex. B ¶¶ 45-140.) In particular, Dr. Wilkes points to persuasive (factor 4). (Wilkes Aff. evidence of nonobviousness, REDACTED ¶ 30-34, 38-45; Ex. B ¶ 141-146.) In making obviousness determinations, the Federal

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Circuit has stated, "when material facts are disputed, and testimonial, documentary, and expert evidence are needed for their resolution, summary adjudication is not indicated." Quad Envil., 946 F.2d at 872. Because numerous material facts relevant to the Graham factors are in dispute, summary judgment should not be granted on obviousness.

No motivation to orient the Gilbert Film or Allied News Release 2. Film C and no expectation of success in doing so.

For a claim to be obvious, there must be "a reason, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the references, and that would also suggest a reasonable likelihood of success." Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1356 (Fed. Cir. 1999). "This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not 'evidence." Brown & Williamson Tobacco Corp. v. Philip Morris, Inc., 229 F.3d 1120, 1125 (Fed. Cir. 2000); Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340, 1348-49 (Fed. Cir. 2000).

It is not sufficient for the moving party to show it would have been "obvious to try" to make the claimed invention, there must be a reasonable expectation of success. In re O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988). References that teach away from the claimed invention, or which conflict with one another cannot show a motivation to combine such references, or show an expectation of success. Winner, 202 F.3d at 1350; Karsten Mfg. Cop. v. Cleveland Golf Co., 242 F.3d 1376, 1385 (Fed. Cir. 2001); Tec Air, Inc. v. Denso Mfg. Mich., Inc., 192 F.3d 1353, 1360 (Fed. Cir. 1999). Moreover, the prior art as a whole must be considered. Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co., 730 F.2d at 1452, 1462 (Fed. Cir. 1984).

First, for motivation to orient the Gilbert Film or Allied News Release Film C, Pechiney simply refers to the known benefits of orientation in the mid-1980's. (P.S.J., pp. 35-

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36.) However, that some advantages of orientation were known in the prior art is <u>not</u> enough of a specific motivation to orient the Gilbert Film or the Allied News Release Film C to arrive at a claimed invention. *See Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 726 (Fed. Cir. 1990) (court rejecting accused infringer's argument that alleged prior-art's recognition of certain advantages would have provided a sufficient motivation to combine prior art references because such an attempt was nothing more than "hindsight reconstruction;" also rejecting argument that just because all the elements in the claimed invention were known in the art, the invention would have been obvious, since none of the prior art taught the specific combination).

To the contrary, as Cryovac's expert explained orientation would have made these already very thin films thinner (assuming that such orientation was even possible) and would have therefore reduced the desirable barrier properties of these films. (Wilkes Aff. ¶ 48.) Thus, there would have been no motivation to orient these specific films. *Id.*; see Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1053 (Fed. Cir. 1988); Wilkes Aff. ¶¶ 46-52. Furthermore, one of ordinary skill making a film must balance many different competing considerations, including the known drawbacks of using nylon, and the difficulty in orienting films containing EVOH and nylon. (Wilkes Aff. ¶¶ 26-34.) By not proving there was a motivation for one of ordinary skill in the art to orient the Gilbert Film or the Allied News Release Film C--assuming such films existed at all--Pechiney has failed to meet this "essential evidentiary component of an obviousness holding." C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1352 (Fed. Cir. 1998).

Second, based on the prior art as a whole, a person of ordinary skill in the art would <u>not</u> have had the requisite expectation of success in orienting either the Gilbert Film or the Allied News Release Film C. (Wilkes Aff. ¶ 25-37, 46-52.) Prior art REDACTED 'show instead that when Shah's invention was made, films containing EVOH and

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nylon were considered difficult to orient. (Wilkes Aff. ¶¶ 30-37.) Even one of the patents Pechiney cites (the '854 patent) contains teachings against orienting a film with the structure of the Gilbert Film or the Allied News Release Film C.²⁵ (Ex. W at col. 1, Ins. 48-54.)

Pechiney seems to argue there would have been an expectation of success to orient the Gilbert Film or Allied News Release Film C in light of the '355 or '854 patents. (P.S.J., pp. 35-37.) As discussed in footnote 6 above, the '355 patent disclosing orientation of a film containing "nylon/EVOH/nylon" would hardly create a reasonable expectation of success in orienting films such as the Gilbert Film or the Allied News Release Film C, which are significantly different films with more than twice the number of layers in a different arrangement, adding additional types of layers with a different manufacturing process (coextrusion) than that suggested in the '355 patent. (P.S.J., pp. 36-37; Wilkes Aff. ¶ 30-37; Ex. B ¶ 41, 59-66.)

Likewise, as discussed in footnote 7, the '854 patent discloses a significantly different layer structure than the films Pechiney is suggesting to orient. (Ex. B ¶ 121-127; Ex. W.) The '854 films do not contain any intermediate nylon layers on either side an EVOH core layer. (Ex. M at 110:5-9; Ex. B ¶ 121.) Rather, the '854 patent teaches a critical modified polyolefin layer adjacent to at least one side of the EVOH layer, which the '419 patent does not teach. (Ex. M at 120:14-22; 121:18-122:15:) Moreover, the '854 patent taught that this critical polyolefin layer, positioned adjacent to the EVOH layer, was needed because prior EVOH films "cannot be produced by extruding all of the layers simultaneously to obtain an orientation of all layers by stretching under identical conditions." (Ex. W at col. 1, lns. 48-54.) Given these disclosures in the '854 patent, there would have been no expectation of

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²⁵ A prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1547, 1550 (Fed. Cir. 1983).

successfully orienting the Gilbert Film or the Allied News Release Film C--which Pechiney alleges are coextruded films containing both nylon and EVOH layers. (Ex. B ¶¶ 38-44, 121-133; Wilkes Aff. ¶¶ 30-37; Ex. D at 229:14-234:20.) Because there was prior art which clearly taught away from orienting films such as the Gilbert Film and the Allied News Release Film C, there would not have been the requisite expectation of success. (Wilkes Aff. ¶¶ 30-37, 46-52; Ex. FF at 158:21-161:2.)

Thus, summary judgment should not be granted for the additional reason that Pechiney failed to prove by clear and convincing evidence that one of ordinary skill in the art would have had both a motivation to orient the Gilbert Film or the Allied News Release Film C, a reasonable expectation of success in doing so (based on the prior art as a whole), or that such a procedure would produce the film of Shah's claim 11.26

3. Objective indicia of non-obviousness

The court must consider any objective indications of nonobviousness offered by the patentee <u>before</u> determining whether an invention is obvious--assuming the patentee has shown a nexus or relevance between the claimed invention and any secondary considerations.²⁷

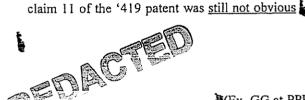
²⁶ Pechiney asserts that "the '419 patent teaches nothing new about how to orient films;" but the two publications it cites (by Benning) do not disclose any films covered by claim 11, or explain how to orient multilayer coextruded films described in claim 11. (P.S.J., p. 38.) Rather, Benning is only referring to the orientation of single layer, single component films. (Wilkes Aff. ¶ 50.) In contrast, the '419 specification does teach something "new about how to orient films." *Id.* The '419 specification, including the two working examples teaches how to orient coextruded films having the layer structure recited in claim 11. (Wilkes Aff. ¶¶ 53-55; Ex. A at col. 3, Ins. 30-40, 45-52, col. 7, Ins. 14-34, col. 8, Ins. 60-68.)

²⁷ In this case there is a "nexus between the merits of the claimed invention and the secondary considerations" because the documents showing nonobviousness are specifically discussing the ClearShield™ product and the benefits of an oriented, coextruded film with the layer structure poly/tie/nylon/EVOH/nylon/tie/poly (as set forth in claim 11). Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 306 n.42 (Fed. Cir. 1985); Ex. R at PPPI 008164-65; Ex. GG at PPPI 007881. Furthermore, if the marketed product embodies the claim features, then a nexus is presumed and the burden shifts to the party asserting obviousness to present evidence to rebut the presumed nexus. Brown & Williamson, 229 F.3d at 1130 ("Our case law provides that the success of an infringing product is considered to be evidence of the

Lindemann, 730 F.2d at 1461; Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563, 1570 (Fed. Cir. 1996) (district court is "required to consider" evidence of unsuccessful attempts by others in determining whether the accused infringer has proved obviousness by clear and convincing evidence).

In addition to raising genuine issues of material fact which preclude summary judgment,²⁸ secondary considerations "may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was <u>not</u>." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) (emphasis added).

Here, unambiguous, undisputed evidence shows that Mr. Shah's invention covered by



(Ex. GG at PPPI 007881; Ex. A at col. 3, Ins. 6-19, col. 8,

Ins. 35-43, col. 7, Ins. 62-64; Wilkes Aff. ¶ 32-34, 38-40.)





🕈 (See

Fin Ex. R at PPPI 008164-65; Wilkes Aff. ¶¶ 39-40; Ex. B

¶¶ 141-143.)



commercial success of the claimed invention."). The LID1050 sold by Cryovac, and the ClearShield™ sold by Pechiney both fall within claim 11 and are both commercially successful. (Wilkes Aff. ¶¶ 41-45; Ex. B ¶¶ 144-146; Ex. JJ; Ex. C ¶¶ 9-11; Ex. S.) Thus, a nexus is also presumed in this case.

²⁸ See Cont'l Can, 948 F.2d at 1273-74; Pro-Mold & Tool Co., Inc. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1574 (Fed. Cir. 1996).

Pechiney's current litigation-induced arguments. (Wilkes Aff. ¶ 45.) As the Federal Circuit stated:

Indeed, the litigation argument that an innovation is really quite ordinary carries diminished weight when offered by those who had tried and failed to solve the same problem, and then promptly adopted the solution that they are now denigrating.

Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc., 21 F.3d 1068, 1072 (Fed. Cir. 1994); see also In re Hayes Microcomputer Prods., Inc. Patent Litig., 982 F.2d 1527, 1540 (Fed. Cir. 1992) (commercial success of product covered by claim is part of "compelling objective evidence of the nonobviousness of the claimed invention").

A reasonable jury could certainly find that the films described in claim 11 were not obvious based on this objective evidence of nonobviousness alone, and therefore summary judgment on obviousness should not be granted for this additional reason as well.

F. **ENABLEMENT**

The party asserting invalidity bears the burden of proving facts by clear and convincing evidence which establish that the patent's specification (along with knowledge in the prior art) did not enable one to make and use the claimed invention. Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1359 (Fed. Cir. 1998). "[I]t is imperative when attempting to prove lack of enablement to show that one of ordinary skill in the art would be unable to make the claimed invention without undue experimentation." Id. at 1360 (emphasis in original). In other words, the accused infringer must provide evidence that "the trial and error required to practice the claimed invention would be unduly laborious or beyond the reach of one of ordinary skill in the art." Koito Mfg., Co., Ltd. v. Turn-Key-Tech, LLC, 381 F.3d 1142, 1155-56 (Fed. Cir. 2004).

"Whether undue experimentation is needed [to make and use an invention] is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). "The determination

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of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art." Id. "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." Id. "Factors to be considered in determining whether a disclosure would require undue experimentation ... include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." Id.

Pechiney offered no evidence showing that in March 1986 (the filing date of the '419 patent) one of ordinary skill in the art would have been unable to make the films covered by claim 11 without "undue experimentation" or that any trial and error required to make the films "would be unduly laborious or beyond the reach of one of ordinary skill in the art." Koito, 381 F.3d at 1155; Johns Hopkins, 152 F.3d at 1360; P.S.J., pp. 37-38. Nor did Pechiney discuss any of the numerous "Wands factors" relevant to a non-enablement argument. See In re Wands, 858 F.2d at 737; Boston Scientific SciMed, Inc. v. Cordis Corp., 392 F.Supp.2d 676, *4 (D. Del. Oct. 14, 2005) (summary judgment on non-enablement denied because "[Defendant] has not specifically discussed any of the [eight] 'Wands factors' and, while asserting that experimentation would be needed to practice the claimed invention, has failed to show that any such experimentation would be undue.").

The '419 patent specification, in fact, provides far more than "the mere germ of an idea." (P.S.J., p. 20, quoting Genentech at 1366.) The '419 specification provides detailed guidance concerning polymer components for the various layers, the inclusion of additives

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(e.g., slip and antiblock agents), and two working examples making films covered by claim 11. (Wilkes Aff. ¶ 54-55; Ex. A at col. 5, In. 6-col. 6, In. 64; col. 5, Ins. 35-40; col. 6, Ins. 3-14.) The '419 patent examples also provide specific layer compositions and detailed formation methods, including temperature and stretch conditions used to orient the coextruded and cooled multilayer films. (Wilkes Aff. ¶ 54-55; Ex. A at col. 7, ln. 1-col. 8, ln. 34; col. 7, lns. 14-23.) Thus, the detailed disclosure in the '419 specification was enabling. See PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1565 (Fed. Cir. 1996) ("Where the specification provides 'guidance in selecting the operating parameters that would yield the claimed result,' it is fair to conclude that the experimentation required to make a particular embodiment is not 'undue.'") (citations omitted).

Cryovac's experts Dr. Wilkes and Dr. Kimmel also provided their opinion that based on the detailed disclosure in the '419 specification and what was known in the art, one of ordinary skill in the art would have been able to make and use the invention of claim 11 without undue experimentation. (Wilkes Aff. ¶¶ 54-55; Ex. D at 16:14-19, 109:11-117:13; Ex. FF at 157:12-158:9.) Pechiney has not offered any contrary expert opinion. Rather, the only evidence Pechiney relies on is the deposition testimony of a Cryovac technician, Mr. Kay. (P.S.J., pp. 37-38.) Pechiney's reference to Mr. Kay's deposition testimony, however, is REDACTED inapt, since:

(Ex. T at 186:11-14.)

REDACTED

Moreover, Mr. Kay

(Ex. T at 6:3-7:13, 8:7-16.)

Because Pechiney has not proven by clear and convincing evidence that one of ordinary skill in the art could not have made the films described in claim 11 without undue experimentation, Pechiney is not entitled to summary judgment on non-enablement.

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IV. CONCLUSION

For the reasons set forth above, Pechiney has not shown that it is entitled to summary judgment. Therefore, Pechiney's Motion for Summary Judgment on Patent Issues must be denied.

Dated: November 18, 2005

Respectfully submitted,

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Attorneys for Plaintiff, CRYOVAC, INC.

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PHARMASTEM THERAPEUTICS, INC., Plaintiff, v. VIACELL INC., CRYO-CELL INTERNATIONAL, INC., CORCELL, INC., STEMCYTE, INC., CBR SYSTEMS, INC. f/k/a CORD BLOOD REGISTRY, INC., BIRTHCELLS TECHNOLOGY, INC., NUSTEM TECHNOLOGIES, INC., and BIO-CELL, INC., Defendants.

C.A. No. 02-148 GMS

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

2003 U.S. Dist. LEXIS 17137

September 30, 2003, Decided

SUBSEQUENT HISTORY: Motion for new trial granted by, in part, Motion to strike denied by, Injunction denied by, Motion denied by Pharmastem Therapeutics v. Viacell Inc., 2004 U.S. Dist. LEXIS 18638 (D. Del., Sept. 15, 2004)

PRIOR HISTORY: Pharmastem Therapeutics, Inc. v. Viacell Inc., 2003 U.S. Dist. LEXIS 3047 (D. Del., Feb. 26, 2003)

DISPOSITION: [*1] Plaintiff's Motion In Limine to Exclude Decision of European Patent Office From Evidence was granted.

LexisNexis(R) Headnotes

COUNSEL: For Pharmastem Therapeutics Inc, PLAINTIFF: Philip A Rovner, Potter Anderson & Corroon, LLP, Wilmington, DE USA.

For Viacell Inc, DEFENDANT: Jeffrey L Moyer, David Allan Felice, Richards, Layton & Finger, Wilmington, DE USA.

For Cyro-Cell International Inc, Corcell Inc, Stemcyte Inc, Birthcells Technology Inc, Bio-Cell Inc, DEFENDANTS: Robert F Stewart, Jr, Dilworth Paxson LLP, Wilmington, DE USA.

For CBR Systems Inc, DEFENDANT: Richard D Kirk, Morris, James, Hitchens & Williams, Wilmington, DE USA.

JUDGES: Gregory M. Sleet, UNITED STATES DISTRICT JUDGE.

OPINIONBY: Gregory M. Sleet

OPINION:

MEMORANDUM AND ORDER

I. INTRODUCTION

On August 5, 2003, PharmaStem Therapeutics, Inc. ("PharmaStem") filed a motion in limine to exclude from evidence the July 21, 1999 decision of the European Patent Office ("EPO") revoking one of PharmaStem's related European patents (the "EPO Decision"). On August 12, 2003, Viacell Inc., Cryo-Cell International, Inc., Corcell, Inc., Stemcyte, Inc., CBR Systems, Inc. f/k/a Cord Blood Registry, Inc., Birthcells Technology, [*2] Inc., Nustem Technologies, Inc., and Bio-Cell, Inc. (collectively "Viacell") filed an answer to PharmaStem's motion, and on August 15, 2003, PharmaStem filed a reply. The court conducted a pretrial conference on September 8, 2003 in which it heard oral argument from the parties on PharmaStem's motion. Upon consideration of the arguments raised at the pretrial conference and in the parties' briefs, the court will grant PharmaStem's motion in limine. The EPO Decision is not admissible evidence. The court bases its ruling on the following reasons.

II. DISCUSSION

The EPO Decision revokes PharmaStem's European patent that is related to its '681 patent presently at issue. The decision applies European, as opposed to United States, patent laws, and examines different claims than the ones at issue in this case. In the opinion, the EPO cites a 1997 article written by Hal Broxmeyer (the "Broxmeyer Article"), one of the inventors of the patents-in-suit. Published nearly ten years after the initial filing of the patents-in-suit, the Broxmeyer Article is not a prior art reference. The EPO cited the Broxmeyer Article for the proposition that the relevant scientific community considered [*3] progenitor cell assays to be reliable assays for stem cells. In addition, the EPO found that Koike, a prior art reference that PharmaStem also cited to the PTO, discloses stem cells.

The EPO Decision was published on July 21, 1999. A little over eight months later, the United States Patent and Trademark Office ("PTO") finished a near seven-year reexamination proceeding of PharmaStem's '681 patent and issued the reexamination certificate on April 11, 2000. Before the EPO Decision came out, PharmaStem argued to the PTO during the reexamination proceedings that Koike did not teach stem cells. In the intervening time period between the EPO Decision and the PTO's reissue of the '681 patent, PharmaStem did not cite the Broxmeyer Article to the PTO. Nor did PharmaStem disclose to the PTO the EPO's finding that the Koike reference teaches stem cells.

Viacell claims that the EPO Decision is relevant to these proceedings because it illustrates the materiality of the Broxmeyer Article and therefore supports Viacell's argument that PharmaStem engaged in inequitable conduct by failing to disclose the article to the PTO. Viacell further contends that the EPO's factual findings regarding the Koike [*4] reference may have been important to a reasonable patent examiner in deciding whether to reissue the patents-in-suit. According to Viacell, the EPO Decision therefore must be admitted into evidence so that the jury may evaluate the EPO's factual determination that Koike discloses stem cells. Finally, Viacell claims that the EPO's finding of invalidity is relevant to its defense against PharmaStem's willful infringement claim because it confirms the reasonableness of the opinions of counsel upon which some of the defendants in this case relied. The court disagrees.

The EPO Decision cites the Broxmeyer Article in the portion of its opinion on novelty. The relevant language of the opinion states, "It appears undoubtful to the Opposition Division that there is a broad consensus in the scientific community as to the reliability of surrogate assays for progenitors, such as assays for CFU-GM, as indirect evidence for the presence of stem cells in a sample, as shown for example by the patent itself (paragraphs 6.6.3 and 6.8) and other documents, e.g., D21, D143 [the Broxmeyer Article] and D145." Decision Revoking the European Patent (Article 102(1) EPC) at 22. The EPO's mention of the Broxmeyer [*5] Article in this regard, at best, marginally supports Viacell's position that the Broxmeyer Article is material information. Indeed, the EPO itself refers to the article as an example of "indirect evidence" and cites it merely to refute PharmaStem's argument that progenitor cell assays were not predictive of the presence of stem cells. nl

n1 Notably, the index of the EPO Decision lists at least 140 references.

Similarly, the fact that the EPO Decision cited the article in this particular context has very little bearing on the issue of PharmaStem's intent to deceive the PTO. Applicants do have a duty to disclose to the PTO "any material prior art or other information cited or brought to their attention in any related foreign application." Manual of Patent Examining Procedure § 2001.06(a) (4th ed., rev. 8, Oct. 1981). However, a finding of inequitable conduct for nondisclosure of information requires proof that the applicant made a deliberate decision to withhold a known material reference from the PTO. See [*6] Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995). Given the EPO's peripheral reliance on the Broxmeyer Article, the relatively short period of time between the EPO and PTO decisions, and the fact that the Broxmeyer Article is not a prior art reference to the patents-in-suit, the EPO Decision has little probative value suggesting that PharmaStem thought the Broxmeyer Article was material and deliberately failed to disclose it to the PTO.

The EPO Decision's probative value is further diminished in view of the high standard of proof required to establish inequitable conduct. "One who alleges inequitable conduct arising from a failure to disclose prior art must offer clear and convincing proof of the materiality of the prior art, knowledge chargeable to the applicant of that prior art and of its materiality, and the applicant's failure to disclose the prior art, coupled with an intent to mislead the PTO." Molins, 48 F.3d at 1178; accord Rockwell Techs., LLC v. Spectra Physics Lasers, Inc., 2002 U.S. Dist. LEXIS 5180, 2002 WL 531555, at *3 (D. Del. Mar. 26, 2002). "Materiality and intent to deceive are distinct factual inquiries, and each must be shown [*7] by clear and convincing evidence." Life Techs., Inc. v. Clontech Lab., Inc., 224 F.3d 1320, 1324 (Fed. Cir. 2000); accord Isco Int'l, Inc. v. Conductus, Inc., 279 F. Supp. 2d 489, 2003 U.S. Dist. LEXIS 14939, 2003 WL 22006253, at *6 (D. Del. Aug. 21, 2003). The fact that the EPO cited the Broxmeyer Article under the described circumstances does little to carry Viacell's heavy burden.

Viacell relies on *Molins* for the proposition that PharmaStem's failure to cite the Broxmeyer Article to the PTO after the EPO referred to it constitutes evidence of inequitable conduct requiring admission of the entire EPO Decision. This reliance is misplaced. The circumstances of *Molins* are distinguishable from the present situation. First, unlike the Broxmeyer Article, the reference at issue in *Molins* was prior art. See id. at 1180. Second, PharmaStem argued the validity of its patents to

the PTO before the EPO decision came out. In sharp contrast, the patentee in *Molins* had amended and distinguished its claims around the prior art reference to several foreign patent offices over the course of thirteen years but never disclosed that reference to the PTO. See id. These distinctions are significant. [*8] n2 In this light, the probative value the EPO Decision on the issue of PharmaStem's intent to deceive is outweighed by the substantial risk that admitting the opinion would unfairly prejudice PharmaStem and confuse the jury.

n2 Likewise, the circumstances surrounding this court's decision in *Rockwell* were also vastly distinguishable from the present facts. In *Rockwell*, the alleged material information was also prior art and the patentee had similarly distinguished the references to two different foreign patent offices without disclosing them to the PTO. *Rockwell*, 2002 U.S. Dist. LEXIS 5180, 2002 WL 531555, at *3. Based on those facts, the court determined that genuine issues of material fact existed with regard to the patentee's inequitable conduct. *Id.* 2002 U.S. Dist. LEXIS 5180, at *4.

Federal Rule of Evidence 403 gives the court broad discretion to exclude evidence where "its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, [*9] or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." F.R.E. 403; see, e.g., Betterbox Comms. Ltd. v. BB Techs., Inc., 300 F.3d 325, 330 (3d Cir. 2002) (emphasizing the district court's broad discretion when ruling on a Rule 403 request). An opinion, although of a quasi-judicial or administrative body and albeit that of a foreign jurisdiction, carries with it a certain imprimatur, which creates a substantial risk that the jury will give its conclusions undue deference. Even if the jury is instructed to consider the opinion for its limited purposes, there is a strong likelihood that the jury would be confused as to its relevance. Thus, the EPO's citation to the Broxmeyer Article in a string of exemplary documents supporting its conclusion on one issue relating to novelty is not grounds for admitting the entire decision, particularly where less prejudicial means of making its argument are available to Viacell. Indeed, Viacell can make its argument that the Broxmeyer Article is material and that PharmaStem

knew of its existence by submitting the article itself into evidence.

Viacell's [*10] remaining arguments for the admissibility of the EPO Decision also lack merit. The fact that EPO found that the Koike reference discloses stem cells does not render the entire opinion admissible. It is the role of the jury to make its own factual findings, not to rely on the factual findings of a foreign patent office. Again, Viacell can submit the Koike reference itself into evidence and argue its teachings to the jury.

The EPO Decision's relevance to Viacell's defense to PharmaStem's willful infringement claim also lacks the degree of probative value that would outweigh the opinion's substantial risk of jury confusion and prejudice to PharmaStem. Viacell argues that the EPO's revocation of the related patent confirms the reasonableness of opinions of counsel relied upon by some of the defendants in this case. The opinions of counsel themselves are admissible evidence. Introducing the EPO Decision to buttress these opinions, therefore, would be cumulative, confusing to the jury, and unfairly prejudicial to PharmaStem.

III. CONCLUSION

The court finds the EPO Decision's probative value to be substantially outweighed by the risk of unfair prejudice to PharmaStem and the [*11] likelihood of jury confusion. Because Viacell could accomplish a substantially similar and less prejudicial result by admitting the Broxmeyer Article, the Koike reference, and the legal opinions of counsel themselves, the court will exercise its discretion to exclude the EPO Decision from evidence

Therefore, IT IS HEREBY ORDERED that:

- 1. PharmaStem Therapeutics, Inc.'s Motion In Limine to Exclude Decision of the European Patent Office From Evidence is GRANTED.
- Viacell may not introduce the July 21, 1999 Decision of the European Patent Office into evidence.

Dated: September 30, 2003

Gregory M. Sleet

UNITED STATES DISTRICT JUDGE

CERTIFICATE OF SERVICE

I, Michele Sherretta, hereby certify that on November 18, 2005, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such document is available for viewing and downloading to the following counsel of record:

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I further certify that I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated.

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